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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/723,859

11/26/2003

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EXAMINER

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ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

08/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/723,859
Filing Date: November 26, 2003
Appellant(s): AVINASH ET AL.

John M. Rariden
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the appeal brief filed 28 December 2007 appealing from the Office action mailed 23 July 2007.

PRELIMINARY REMARKS

After further consideration, this application contains at least one claim that does not meet the patent eligibility requirement for statutory subject matter under 35 U.S.C. 101. Accordingly, this examiner's answer contains a new ground of rejection under 35 U.S.C. 101. Appellant must within TWO MONTHS from the date of this answer exercise one of the following options to avoid sua sponte dismissal of the appeal as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

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(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Claims 1-12 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,363,844 Riederer et al. 11-1994

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections – 35 USC § 101

New Grounds of Rejection

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88

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(1876)). See also In re Bilski (Fed Cir, 2007-1130, 10/30/2008) where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-20, 22-32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Riederer et al (US Patent No. 5,363,844), hereinafter referred to as Riederer ('844).

Regarding claims 1-4 and 13-16, Riederer ('844) discloses a method and program including the steps of acquiring a set of motion data during a breath hold, deriving an attribute of motion from the set of motion data, deriving an initiation threshold and termination threshold from the attribute, and generating a set of gated image data using gating intervals derived from the thresholds (col. 5 lines 31-53, col. 6 line 29-36). Riederer ('844) discloses that the set of motion data is acquired from a navigator pulse sequence, which is the same as a acquiring a set of pre-acquisition image data as claimed in the instant application (col. 5 lines 5-58). Riederer ('844) discloses that the displacement of the diaphragm may be detected via the NMR system, which constitutes an electrical sensor, and respiratory bellows, which constitute non-electrical sensors (col. 2 lines 14-15, col. 5 lines 34-37, col. 7 lines 2-6).

Regarding claims 5-8 and 17-20, Riederer ('844) shows that the image data is acquired when a first measurement of motion decreases below an initiation threshold, and acquisition ceases when motion increases above a termination threshold, wherein the beginning and end of the breath hold disclosed by Riederer ('844) constitute the initiation and termination thresholds, respectively, as claimed in the instant application (Fig. 3). Furthermore, the duration of the breath hold disclosed by Riederer ('844) constitutes a quiet period as claimed in the instant application. Riederer ('844) also discloses that the motion measurements are acquired concurrently with the image data (col. 5 lines 37-36).

Regarding claims 10-11 and 22-23, Riederer ('844) states that a respiration monitor is used to detect an acceptable breath-hold, and to generate the respiratory trigger pulse, which is the same as determining if a scan parameter is satisfied and acquiring image data based on the scan parameter as claimed in the instant application (col. 5 lines 48-54). In the method of Riederer ('844), the absence of

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the respiratory trigger pulse when the breath-hold is not acceptable is the same as a notification as claimed in the instant application.

Regarding claims 12 and 24, Riederer ('844) discloses a step and routine for providing a visual notification to the patient indicating breath hold status (col. 6 lines 54-66).

Regarding claims 25-29 and 35, Riederer ('844) discloses an imaging system and computer programs for performing the method of claims 1-12 of the instant application, wherein the system comprising an imager configured to generate a plurality of signals representative of the diaphragm and heart, data acquisition circuitry, data processing circuitry, system control circuitry for generating a set of gated image data, an operator workstation, a sensor-based motion determination system to measure electrical and non-electrical attributes of one or more organs, wherein the sensor-based motion determination system employs respiratory bellows, which constitute pressure sensors (Fig. 1, col. 7 lines 2-6, col. 3 line 4 – col. 5 line 30).

Regarding claim 30, Riederer ('844) provides means for generating gated image data by activating the imager based upon a gating interval (col. 2 lines 11-13).

Regarding claim 31, Riederer ('844) discloses means for generating gated image data by registration, which constitutes selectively processing a plurality of signals based upon gating intervals (col. 2 lines 38-41).

Regarding claim 32, the system of Riederer ('844) includes a color-coded visual feedback device configured to notify the patient of a breath hold status based upon data from a sensor-based motion determination system (col. 6 lines 54-66).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riederer (US Patent No. 5,363,844). Riederer ('844) teaches all features of the present invention as previously described in this Office Action. While Riederer ('844) teaches displaying the motion data and

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determining if the gating intervals are acceptable, Riederer ('844) does not explicitly teach the step of replacing the thresholds or gating intervals if they are determined to be unacceptable (col. 5 lines 48-50). However, it would have been obvious to one of ordinary skill in the art at the time of invention to add this step to the method of Riederer ('844), as it is well known in the art that image data acquired during an unacceptable gating interval is not accurate or useful.

(10) Response to Argument

a) Definition and interpretation of the term "gating"

Appellant alleges that Examiner has made a legal error by improperly relying upon extrinsic evidence to define a term "already fully explained" in the pending specification (Appeal Brief, p. 8-10). Specifically, Appellant purports that Examiner's interpretation of the term "gating" as recited in the instant claims is improper for being "overly expansive" in view of the claim language and the teachings of the instant specification. Appellant references page 1 lines 23-26, page 4 lines 4-7, page 11 lines 11-15 for support of the argument that the term gating was defined as being derived from motion data.

The Examiner maintains that, although the claims have in fact been considered in light of the specification, it is the Examiner's duty to rely upon their broadest reasonable interpretation when determining patentability of those claims in view of the prior art. Nowhere in the above-referenced passages of the pending disclosure does Appellant explicitly set forth a re-definition of the term "gating" from that which is commonly known in the art as meaning *only* initiation and termination of a process based upon motion data. It has previously been held that, where an applicant wishes to act as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that term (*Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 Fed. Cir. 1999). A mere discussion of specific examples of types of gating, as is presented in page 1 lines 23-26, page 4 lines 4-7, page 11 lines 11-15 of the present specification, does not constitute such a statement. Accordingly, it is reasonable and proper for Examiner to rely upon the definition set forth in a general purpose dictionary, such as Merriam Webster, to determine the boundaries of the broadest reasonable interpretation of the term "gating".

b) Termination of imaging based on motion attributes

Appellant contends that the Riederer ('844) reference makes no suggestion that imaging terminates when the diaphragm begins moving, as is relied upon by Examiner in the current grounds of rejection (Appeal Brief p. 10-11). Specifically, Appellant purports that "all instances in the Riederer reference appear to characterize the data acquisition as continuing for a set time period".

While it is true that Riederer ('844) acquires image data for a set time period, Examiner maintains that this set time period does not teach away, nor is it mutually exclusive from the step of terminating image data acquisition at a motion threshold as recited in the current claims. Riederer ('844) states that the breath hold time ("set time period") is determined by using a respiration monitor to observe the acceptable amount of breath hold time for that particular subject, and the reference also goes on to state that "the degree of chest inflation is monitored with NMR measurements of the superior-inferior (S/I) position of the patient's diaphragm" (col. 5 lines 48-53). The length of the breath hold cycle is thus determined from motion data by Riederer ('844), and since image data acquisition is disclosed to occur concurrently to such a breath hold (col. 5 lines 28-30), one of ordinary skill would recognize that, in the reference method, image acquisition terminates at the end of the breath hold (Fig. 3), and this breath hold end constitutes a threshold as claimed. It is inherent that, upon termination of a breath hold, a patient's diaphragm begins to move in order to initiate normal respiration. Therefore, it can be said that Riederer ('844) does in fact terminate imaging at the initiation of diaphragm movement as stated in the previous rejection.

c) Retrospective selection of gated image data

Appellant contends that Riederer ('844) lacks disclosure of steps and means for selection of a set of gated image data from a set of image data (Appeal Brief p. 11). Appellant specifically alleges that the reference does not provide support for retrospective gating as claimed in the instant application.

Riederer ('844) discloses registration of movement data to image data (col. 2 lines 36-41). Such registration must inherently occur post-acquisition, as it is not possible to register two sets of data that have not yet been acquired. Examiner maintains that, by registering the image data to the diaphragm motion data, one is effectively identifying those portions of the image data that respond to the time period of least diaphragm movement, which is disclosed by the reference to be the desirable and useful portion of the image data (col. 1 lines 31-50, col. 2 lines 1-6). Riederer ('844) uses this portion of image data

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acquired during minimal movement to calculate an average dataset that has improved signal-to-noise ratio (col. 2 lines 36-48). By such post-acquisition selection of breath-hold image data, Riederer ('844) does in fact retrospectively gate the data.

d) Determination of whether scan parameters are satisfied

Appellant argues that Riederer ('844) does not disclose the step of determining if one or more scan parameters are satisfied (Appeal Brief p. 11).

Riederer states that "a respiration monitor is required to detect an acceptable breath-hold and to generate the respiratory trigger pulse" (col. 5 lines 48-51). Examiner interprets the step of detecting an acceptable breath-hold to constitute "determining if one or more scan parameters are satisfied" as is currently recited by the instant claims; i.e., the acceptability of the breath-hold is a scan parameter.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Parikha S Mehta/

Examiner, Art Unit 3737

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